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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,294	04/03/2001	Jiangchun Xu	210121.484C5	4060

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EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/27/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/825,294	Applicant(s) XU ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1,2,5-7,9,10,12-14 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,8,11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group I, claims 1, 3, 4, 8, 11-in-part (b), and 15 in paper number 7 filed 6 June 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Information Disclosure Statement

The Information disclosure statement, filed 02/08/02, has been entered and considered. An initialed copy of the form PTO-1449 is enclosed with this action.

Claims Rejections-35 USC 112

Claims 1, 3, 4, 8, 11-in part, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to make and/or use elected SEQ ID NO. 214, presumably for the diagnosis of ovarian cancer. However there are no particulars disclosed as to how to practice this. The only mention of SEQ ID NO. 214 is on page 107 in the specification, as filed. In the third full paragraph, last line, SEQ ID NO. 214 is described as the "consensus sequence for O1034C/O591S of 1879 base pairs". The significance of this information is not disclosed. There is no discussion as to what the sequence designation refers to, nor is it in a readily recognizable form, such as a GenBank Accession Number. For the reasons discussed below, there would be an unpredictable amount if experimentation required to practice the claimed invention.

b) The specification provides examples for generic methods for using the disclosed sequences in a variety of different molecular assays.

c) The specification provides no working examples of using SEQ ID NO. 214 in any particular manner, especially not for the diagnosis or detection of ovarian cancer. There is no evidence that this sequence is connected to the presence or absence of cancer. There is no indication about whether or not various cells are involved or if expression levels are significant in such that the levels must reach a critical level in order for detection? Further, the mere presence of a particular transcript does not speak to whether any encoded protein is produced. The specification does not identify an open reading frame for this sequence nor does it identify any encoded polypeptides. Many genes are potentially transcribed and expressed in cancerous, pre-cancerous, and normal cells. Lacking evidence supporting specificity of the sequence for a particular cell type, one of skill in the art would have reasonable doubt that this particular sequence would be useful as a cancer marker sequence.

d) The invention is drawn to SEQ ID NO. 214.

e) Cancer diagnosis is a complicated, unpredictable field. Of the hundreds of types of cancer known, there are two to three times as many potential "marker" sequences published and studied. It is unlikely that the simple presence or absence of SEQ ID NO.214 could be diagnositic for ovarian cancer. Many so called "tumor" markers in the art have been shown to be present in non-tumor tissues such that one of skill in the art would not have an expectation that any one sequence would be indicative of cancer. For example, the CEA and CA antigens are commonly used as "tumor markers" for recurrent breast cancer, but the presence of those markers only identify 40% of patients having metastatic breast cancer, and both CEA and CA can be elevated in benign (non-cancerous) conditions.

A search of the proior art for known sequences having homology with SEQ ID NO. 214 reveals that McKee et al. (Genomics (1997) vol. 46, no.3:426-434) disclose GenBank Accession Number AF034633, which includes a stretch of 508 complementary identical nucleotides which are actually expressed in brain tissue. This indicates that SEQ ID NO. 214 may not be specific to ovarian cancer cells and that one of skill in the art would need to perform extensive research to determine whether any significant linkages can be found between cancer and the elected sequence.

f) The skill of those in the art of oncology is high.

g) The prior art indicates that tumor diagnosis is a complex and unpredictable field, and the presence of any one particular sequence may not be reliable for the prediction of a specific type of cancer.

h) The claims are broad because they are drawn to the polynucleotides of SEQ ID NO. 214.

The skilled practitioner would first turn to the instant specification for guidance to use SEQ ID NO. 214. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that most single polynucleotides are not necessarily diagnostic for any particular type of cancer. Finally, said practitioner would turn to trial and error experimentation. Therefore, while the skill of art in oncology is high, the lack of information in the specification would lead one to undue experimentation of one of ordinary skill in the art to determine what, if any, cancer is associated with the presence of SEQ ID NO. 214.

Claims Rejections-35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by McKee et al. (Genomics (1997) vol.46, no.3:426-434). McKee et al. disclose a 1,359 base pair open reading frame from fetal brain cDNA which was aligned and found to be a growth hormone in the G protein coupled receptor family (page 430, second column and abstract). This sequence, which is complementary to SEQ ID NO. 214 at positions 1124-1638, meets the limitations set forth in the claims with regard to sequences that hybridize to SEQ ID NO. 214 under moderately stringent conditions.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

August 22, 2002

Lori A. Clow, Ph.D.
Art Unit 1631